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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, et al., Plaintiffs, vs. GILEAD SCIENCES INC., Defendant.	Case No. C 05 4344 SI (BZ) REDACTED SECOND AMENDED COMPLAINT (Filed pursuant to Court Order of March 9, 2009.)

REDACTED

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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, and the STATES OF CALIFORNIA, DELAWARE, FLORIDA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, NEVADA, NEW HAMPSHIRE, NEW MEXICO, TENNESSEE, TEXAS, VIRGINIA, MICHIGAN, GEORGIA, NEW YORK, OKLAHOMA, and DISTRICT OF COLUMBIA, ex rel. [redacted]

Plaintiffs,

vs.

GILEAD SCIENCES INC.,

Defendant.

Case No. C 05 4344 SI (BZ)

SECOND AMENDED COMPLAINT FOR VIOLATION OF FEDERAL FALSE CLAIMS ACT [31 U.S.C. §3729 et seq.]; CALIFORNIA FALSE CLAIMS ACT [Cal. Govt Code §12650 et seq.]; CALIFORNIA STATE INSURANCE FRAUDS PREVENTION ACT [Cal. Ins. Code §1871 et. seq.]; DELAWARE FALSE CLAIMS AND FALSE REPORTING ACT [6 Del. C. §1201]; FLORIDA FALSE CLAIMS ACT [Fla. Stat. Ann. §68.081 et seq.]; HAWAII FALSE CLAIMS ACT [Haw. Rev. Stat. §661-21 et seq.]; ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT [740 Ill. Comp. Stat. §175 et. seq.]; ILLINOIS INSURANCE CLAIMS FRAUD PREVENTION ACT [740 Ill. Comp. Stat. §92]; INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT [I.C. 5-11-5.5] LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW [La. Rev. Stat. §437 et. seq]; MASSACHUSETTS FALSE CLAIMS LAW [Mass. Gen Laws ch.12 §5 et seq.]; NEVADA FALSE CLAIMS ACT [Nev. Rev.Stat. Ann. §357.010 et seq.]; NEW HAMPSHIRE FALSE CLAIMS ACT [N.H. Rev. Stat. Ann. §167:61 et seq.]; NEW MEXICO MEDICAID FALSE CLAIMS ACT [N.M. Stat. Ann. §27-2F-1 et seq.]; NEW MEXICO FRAUD AGAINST TAXPAYERS ACT [2007 N.M. ALS 40 §§ 1 et seq. (not yet codified); TENNESSEE FALSE CLAIMS ACT AND TENNESSEE MEDICAID FALSE CLAIMS ACT [Tenn. Code Ann. §§4-18-101 et seq. and 71-5-181 et seq.]; TEXAS MEDICAID FRAUD PREVENTION LAW [Tex. Hum. Res. Code Ann §36.001 et seq.]; VIRGINIA FRAUD AGAINST TAXPAYERS ACT [Va. Code Ann §8.01-216.1 et seq.]; MICHIGAN MEDICAID FALSE CLAIMS ACT [MCL 400.601-400.613], GEORGIA FALSE MEDICAID CLAIMS ACT [O.C.G.A. §§ 49-4-168 et seq.], NEW YORK FALSE CLAIMS ACT [N.Y. State Fin. §§ 187 et.

seq.]; OKLAHOMA MEDICAID FALSE CLAIMS ACT [2007 OK. ALS 137 (not yet codified)]; and DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT [D.C. Code Ann. §2-308.14]

JURY TRIAL DEMANDED

(FILED IN CAMERA AND UNDER SEAL)

Plaintiff-Relator [redacted] ("Relator"), through [redacted] attorneys Phillips & Cohen LLP, on behalf of the United States of America, the State of California, the State of Delaware, the State of Florida, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the State of Massachusetts, the State of Nevada, the State of New Hampshire, the State of New Mexico, the State of Tennessee, the State of Texas, the State of Virginia, the State of Michigan, the State of Georgia, the State of New York, the State of Oklahoma, and the District of Columbia (collectively "the States"), for [redacted] Complaint against defendant Gilead Sciences Inc. ("Gilead") alleges based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the States arising from false and/or fraudulent statements, records, and claims made and caused to be made by defendant and/or its agents, employees and co-conspirators in violation of the Federal False Claims Act, 31 U.S.C. §§ 3729 et seq., and the false claims acts and insurance fraud prevention acts of the States set forth below.

2. Gilead develops and sells prescription drugs for the treatment of infectious diseases. The bulk of its sales--$1.4 billion of its total sales of $2 billion for 2005—comes from its three medications for the treatment of HIV/AIDS—Viread, Emtriva and Truvada. Truvada is Gilead's most recent HIV drug, and combines the active ingredients from Viread and Emtriva into a "once-daily" combination pill. Gilead also markets a major drug for the treatment of Hepatitis C, called Hepsera.

3. Gilead's HIV and other drugs are extremely profitable. For 2005, Gilead reported approximately $800 million in net income on $2 billion in sales – a 40% profit margin. The

majority of that revenue and profit comes from prescriptions that are reimbursed by the government. The major government programs that pay for HIV medications are Medicaid, Medicare, state and federal departments of corrections, and government-funded AIDS Drug Assistance Programs and AIDS Services Organizations.

4. Since at least 2001, Gilead has engaged in an unlawful systematic program to boost sales of its prescription drugs by paying kickbacks to physicians to prescribe Gilead products and to listen to Gilead's promotional presentations. Gilead uses these presentations to disseminate FDA-approved, "on-label" promotional information regarding its drugs, but also to make claims and present information that are outside of its drugs' approved labels, and therefore forbidden under FDA drug marketing regulations. These efforts have been planned and directed at the highest levels of Gilead's management.

5. Under the federal Anti-Kickback Statute and similar state laws, a manufacturer may not give anything of value to a physician to induce him or her to prescribe its drugs or listen to its promotional presentations. Accordingly, Gilead disguises its payments to make them appear to fall within limited "safe harbor" exceptions to the Anti-Kickback Statute. First, Gilead funnels millions of dollars in kickbacks to physicians in the form of "payments" made pursuant to sham personal services contracts between those physicians and the company. For example, Gilead pays physicians a per-patient fee for their assistance in conducting studies on Gilead drugs, but in fact many of these studies are little more than a means to funnel cash payments to prescribing physicians and induce them to switch their patients to Gilead drugs from its competitors' drugs. Gilead also purports to train physicians to speak on behalf of the company, when in fact these training programs are simply a means to pay hundreds of physicians cash and non-cash (travel accommodations, meals, etc.) remuneration in exchange for the physicians' prescribing of Gilead drugs and their attendance at promotional presentations. Additionally, while federal regulations permit drug manufacturers to underwrite Continuing Medical Education ("CME") programs, Gilead uses CME sponsorship as a vehicle to provide physicians with valuable CME credits, again to induce them to write prescriptions for Gilead drugs and to listen to Gilead promotional presentations.

6. Gilead's illegal inducements have reached hundreds (if not thousands) of HIV prescribers in the United States. In addition, Gilead focused special attention on a select subset of those physicians who were particularly important to its drug sales, physicians who had especially large patient populations, or had special influence over other prescribers, or had publicly challenged Gilead's marketing message. These physicians received very substantial remuneration from Gilead, in the form of speaking honoraria, and/or membership on special "advisory boards," and/or fees for authoring CME program materials.

7. The payment of inducements—in cash or in any other form—where any part of the purpose of such payments is to influence a physician's prescribing decisions, is explicitly forbidden by federal law, state law, and by the pharmaceutical industry's own guidelines (the so-called "PhRMA Code"). These anti-kickback laws are designed to ensure that physicians prescribe medications based upon informed, impartial medical judgment—judgment unaffected by personal financial motives. In this case, Gilead corrupted the medical decision-making process and put patient health at risk by influencing prescribing practices through valuable kickbacks. Each claim for reimbursement for an illegally-induced prescription represents a false or fraudulent claim for payment, in violation of the federal and state false claims acts.

8. Gilead's conduct in this case is particularly egregious because the company willfully ignored federal agency guidance issued to the pharmaceutical industry in 2003 by the Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS"), as well as the PhRMA Code (a pharmaceutical manufacturers' code of conduct that Gilead purports to abide by).

9. Gilead's conduct alleged herein violates the Federal Civil False Claims Act ("FCA"), 31 U.S.C. §3729 et seq., as well as the FCA's state-law counterparts. The FCA was originally enacted during the Civil War, and was substantially amended in 1986. Congress enacted the 1986 amendments to enhance and modernize the government's tools for recovering losses sustained by frauds against it. The amendments were intended to create incentives for individuals with knowledge of fraud against the government to disclose the information, and to encourage the private bar to commit resources to prosecuting fraud on the government's behalf.

10. The FCA prohibits knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval. 31 U.S.C. §3729(a)(1). Additionally, it prohibits knowingly making or using a false or fraudulent record or statement (a) to get a false or fraudulent claim paid or approved by the federal government or (b) to conceal, avoid, or decrease an obligation to pay or transmit money or property to the federal government. 31 U.S.C. §§3729(a)(2), (a)(7). Any person who violates the FCA is liable for a civil penalty of up to $11,000 for each violation, plus three times the amount of the damages sustained by the United States. 31 U.S.C. §3729(a)(7).

11. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States, and to share in any recovery. The FCA requires that the Complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the government time to conduct its own investigation and to determine whether to join the suit.

12. As set forth below, Gilead's actions alleged in this Complaint also violate the California False Claims Act, Cal. Govt Code §12650 et seq.; the California Insurance Frauds Prevention Act, Cal. Ins. Code §1871 et seq.; the Delaware False Claims and False Reporting Act, 6 Del. C. §1201 et seq.; the Florida False Claims Act, Fla. Stat. Ann. §68.081 et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175/1-8; the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. §92; the Indiana False Claims and Whistleblower Protection Act [I.C. 5-11-5.5]; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §437 et seq.; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§357.010 et seq.; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. §167:61 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-2F-1 et seq.; the New Mexico Fraud Against Taxpayers Act, 2007 N.M. ALS 40 §§ 1 et seq. (not yet codified); the Tennessee False Claims Act, and Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§4-18-101 et seq. and 71-5-181 et seq.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code

Ann. §§8.01-216.1 et seq.; the Michigan Medicaid False Claims Act, MCL 400.601-400.613; the Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168 et seq.; the New York False Claims Act, N.Y. State Fin. §§ 187 et. seq.; the Oklahoma Medicaid False Claims Act, 2007 OK. ALS 137 (not yet codified); and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§2-308.14 et seq.

13. Based on these provisions, Relator seeks to recover all available damages, civil penalties, and other relief for federal and state violations alleged herein, in every jurisdiction to which Gilead's misconduct has extended.

II. PARTIES

14. Plaintiff/Relator [redacted] ("Relator") [redacted].

15. Defendant Gilead Sciences, Inc. is a Delaware corporation with headquarters in Foster City, California. Gilead is engaged in the development, manufacture and marketing of pharmaceuticals throughout North America, Europe and Australia. Since the launch of its HIV drug Viread in 2002, Gilead has grown from a relatively small (and unprofitable) biotech company to become the fourth-ranked biotech company in the world, with annual sales of $2 billion and gross profits of $800 million in 2005. Because the cost of HIV treatment is largely born by public programs, the majority of Gilead's revenue (and profit) comes from federal and state treasuries.

III. JURISDICTION AND VENUE

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1367, and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. In addition, 31 U.S.C. §3732(b) specifically confers jurisdiction on this Court over the state law claims asserted in Counts 3, 5-8, and 10-23 of this Complaint. Jurisdiction over the state law claims asserted in Counts 4 and 9 is based on this Court's supplemental jurisdiction. Under 31 U.S.C.

§3730(e), and under the comparable provisions of the state statutes listed in ¶ 12 above, there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

17. This Court has personal jurisdiction over Gilead pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because Gilead has minimum contacts with the United States. Moreover, Gilead can be found in and transacts business in this District.

18. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because Gilead can be found in and transacts business in this District. At all times relevant to this Complaint, Gilead regularly conducted substantial business within this District, maintained employees in this District, and/or made significant sales within this District. In addition, statutory violations, as alleged herein, occurred in this District.

IV. APPLICABLE LAW

A. The Federal Anti-Kickback Statute Prohibits Payments to Induce Physicians to Prescribe a Manufacturer's Drug.

19. The federal health care Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to over-utilization or poor quality of care.

20. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend drugs that may be paid for by a federal health care program. Id. The law not only prohibits outright bribes and rebate schemes, but also forbids any payment by a drug company that

has as one of its purposes inducement of a physician to write additional prescriptions for the company's pharmaceutical products.

21. Violation of the Anti-Kickback Statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§1320a-7(b)(7), 1320a-7a(a)(7).

22. In May 2003, office of the Inspector General of the Department of Health and Human Services released a formal guidance to pharmaceutical manufacturers, identifying several marketing practices that run a high risk of violating the Anti-Kickback Statute. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003) (the "OIG Guidance"). The OIG Guidance states:

> Any time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer's product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals.

Id. at 23737 (emphasis added).

23. The OIG Guidance stresses that "under the anti-kickback statute, neither a legitimate purpose for an arrangement (e.g., physician education), nor a fair market value payment, will necessarily protect remuneration if there is also an illegal purpose (i.e., the purposeful inducement of business)." Id. at 23737.

24. The OIG Guidance embraces the code of conduct adopted by the Pharmaceutical Research and Manufacturers of America (PhRMA), a voluntary association of the country's leading pharmaceutical companies. Effective July 1, 2002, PhRMA adopted a new marketing code entitled "Code on Interactions with Healthcare Professionals" (the "PhRMA Code"). Like the OIG Guidance, the PhRMA Code highlights a number of marketing and sales practices that are improper under the Anti-Kickback Statute and other laws, and provides guidance on how manufacturers can avoid running afoul of those legal restrictions.

25. In addition to prohibiting kickbacks generally, the OIG Guidance and the PhRMA Code caution manufacturers against engaging in certain specific practices, including the following:

26. Improper Switching Arrangements: The OIG explicitly warned against the payment to physicians for each patient he or she switches to the manufacturer's drug from a competing product. "This activity clearly implicates the statute, and, while such programs might be permissible in certain managed care arrangements, manufacturers should review very carefully any marketing practices utilizing 'switching' payments in connection with products reimbursable by federal health care programs." OIG Guidance at p. 23738.

27. Payments for Detailing: The OIG specifically warned manufacturers against paying physicians simply to listen to promotional presentations:

> In some cases, these payments are characterized as 'consulting' fees and may require physicians to complete minimal paperwork. Other companies pay physicians for time spent accessing web sites to view or listen to marketing information. All of these activities are highly suspect under the anti-kickback statute, are susceptible to fraud and abuse, and should be strongly discouraged.

OIG Guidance, at p. 23738.

28. Sham "Services Contracts": In an attempt to circumvent the prohibition against making payments to prescribers, manufacturers may attempt to set up sham "personal services" contracts with those prescribers, and make the payments under the guise of fees or other remuneration paid pursuant to those contracts. For example, manufacturers purport to hire their physician-customers as speakers or consultants or drug study investigators. While the Anti-Kickback Statute permits legitimate services contracts between manufacturers and physicians, this exception is limited and subject to certain requirements that are meant to guarantee that the arrangements are bona fide. Specifically, the OIG warned that such contracts are legal only where (1) they are not intended in any part to influence physicians' prescribing decisions; (2) the payments to physicians are at "fair market value"; (3) the physicians actually perform bona fide services to the manufacturer (e.g., the physicians' role as "consultant" cannot be simply "to attend meetings or conferences primarily in a passive capacity"); and (4) the manufacturer employs only

a "small number" of physicians (i.e., only that number reasonably required to perform the services). OIG Guidance, at p. 23738.

29. The OIG Guidance counsels manufacturers to ensure that their personal services contracts meet the requirements of the Anti-Kickback Statute's "safe harbor" provisions, codified at 42 C.F.R. § 1001.952(d). The safe harbor provisions require that personal services contracts meet the four criteria listed above. In addition, they require that "[t]he services performed under the agreement do not involve the . . . promotion of a business arrangement or other activity that violates any State or Federal law." Id. at (d)(6).

30. Similarly, the PhRMA Code prohibits "token consulting or advisory arrangements" that are used "to justify compensating healthcare professionals" for time, travel, meals and other expenses. PhRMA Code, Exh. A. The PhRMA Code further provides that, for these arrangements to be legitimate: (1) the physician must provide a bona fide business service to the manufacturer; (2) the manufacturer must have a legitimate need for the services; and (3) the manufacturer must not enter these arrangements with more physicians "than the number reasonably necessary to achieve the identified purpose." Id.

31. Meals, Entertainment & Travel: The OIG warned that the provision of meals, entertainment, travel, or recreational activities to a physician (other than those physicians legitimately employed by the manufacturer as bona fide speakers, consultants, etc.) "potentially implicate[s] the anti-kickback statute if any one purpose of the arrangement is to generate business for the pharmaceutical company." Id. The PhRMA Code forbids a manufacturer's provision of travel, entertainment or recreational activities to physicians. It permits the provision of meals to physicians, but only if they are (1) "occasional"; (2) "modest"; (3) given in association with the provision of "substantial scientific or educational information regarding the company's products;" and (4) provided to the physician alone (i.e., no spouses of friends etc.). PhRMA Code, Exh. A.

31. CME Sponsorship: The OIG warned against using CME sponsorship "to channel improper remuneration to physicians or others in a position to generate business for the manufacturer or to influence or control the content of the program." The OIG further admonished

manufacturers to abide by CME sponsorship rules promulgated by the Food and Drug Administration ("FDA").

32. The FDA permits pharmaceutical manufacturers to sponsor CME programs, but only subject to strict guidelines intended to ensure that CME retains its non-promotional and education character, and that manufacturers do not use CME sponsorship as a marketing tool. In 1997 the FDA published an agency enforcement policy entitled "Guidance for Industry: Industry-Supported Scientific and Educational Activities," 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R.) (1997) (the "CME Guidance"). This document states that CME programs must be truly independent of the sponsoring drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." Id. These factors include, among others, (1) an examination of the relationship between the program provider and the supporting company; (2) the company's control of content and the selection of presenters; (3) whether there is meaningful disclosure of the manufacturers' funding and role in the program; (4) whether multiple presentations of the same program are held; (5) whether the audience is selected by the sales and marketing department of the manufacturer; and (6) whether information about the supporting company's product is disseminated after the initial program other than in response to an unsolicited request.

33. In addition to the CME Guidance, both the pharmaceutical industry and the CME industry have issued guidelines that restrict manufacturers' involvement in CME. The PhRMA Code states that "responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines" (in other words, CME programs should not be under the control of pharmaceutical manufacturers). The Accreditation Council for Continuing Medical Education ("ACCME") has issued its "Standards for Commercial Support – Standards to Ensure the Independence of CME Activities" ("the ACCME Standards"). Among other things, the ACCME Standards require that (a) decisions regarding the selection of CME presenters and program content are made "free of the control" of manufacturers (Standard 1); (b) any financial relationship between a manufacturer and any person in a position to control the content of a CME program

must be disclosed (Standard 2); and (c) CME programs "must promote improvements or quality in healthcare and not a specific proprietary business interest" (Standard 5).

34. Gilead has acknowledged these strict regulatory restrictions by promulgating its own internal CME sponsorship guidelines. These guidelines state that "CME programs must be non-promotional and independent . . . [t]hey may not be controlled or influenced by Gilead" (emphasis added). Specifically, they provide that Gilead (1) will make decisions whether to fund particular CME programs based on applications submitted to it by "independent providers of CME"; (2) will make such funding decisions based on the proposed topic of the CME program alone, not based on the content of the program; (3) will not "participate in program planning or development"; (4) will limit its influence over program content to "respond[ing] to unsolicited requests from the CME provider for speaker suggestions or materials"; and (5) will limit its involvement in CME program promotion to assisting the CME provider with "distribution of invitations or 'save the date' cards on the CME provider's behalf." As discussed below, Gilead's actual CME Sponsorship practices bear no resemblance to its CME guidelines.

35. Compliance with the Anti-Kickback Statute is a precondition to participation as a health care provider in federal health care programs. With regard to Medicare and Medicaid, for example, each physician and pharmacist that participates in the programs must sign a provider agreement with his or her state. Although there are variations in the agreements among the states, the agreement typically requires the prospective Medicare and Medicaid providers to agree that they will comply with all legal requirements, which include the anti-kickback provisions of the law. In a number of states, the Medicare and Medicaid claim form itself contains a certification by the provider that the provider has complied with all aspects of the Medicare or Medicaid program, including compliance with federal laws.

36. In sum, either pursuant to provider agreements, claims forms, or other manner, physicians who participate in a federal health care program must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback Statute.

37. Any party convicted under the Anti-Kickback Statute must be excluded from federal health care programs (i.e., not allowed to bill for services rendered) for a term of at least

five years. 42 U.S.C. §1320a-7(a)(1). Even without a conviction, if the Secretary of HHS finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the federal health care programs for a discretionary period (in which event the Secretary must also direct the relevant State agency to exclude that provider from the State health program), and may consider imposing administrative sanctions of $50,000 per kickback violation. 42 U.S.C. §1320a-7(b).

38. The enactment of these various provisions demonstrates Congress' commitment to the fundamental principle that government health care programs will not tolerate the payment of kickbacks. Thus, compliance with the Anti-Kickback Statute is a prerequisite to a provider's right to receive or retain reimbursement payments from Medicare, Medicaid and other federal health care programs.

39. Similarly, compliance with the federal Anti-Kickback Statute and comparable state anti-kickback statutes is a prerequisite to a provider's right to receive or retain reimbursement payments from state-funded health care programs.

B. Federal Law Prohibits the Use of Misleading or Unsupported Information in the Advertising and Promotion of Prescription Drugs.

40. In addition to forbidding payments to physicians to induce them to prescribe drugs or to attend promotional presentations, federal regulations also limit the form and content of the information a manufacturer may disseminate to physicians in the promotion and marketing of its products. The Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§301-97, prohibits drug companies from making misleading claims as to a drug's safety or effectiveness, from selectively or inaccurately reporting data regarding the drug, and from making unfounded and unapproved claims or superiority to competing products. See 21 U.S.C. §§ 331, 352, 355(d); 21 C.F.R. §202.1(e) & §201.6(a).

41. The FDA specifically prohibits advertising that

> [c]ontains a representation or suggestion, not approved or permitted for use in the labeling, that a drug is better, more effective . . . safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by

> substantial evidence or substantial clinical experience, whether or not such representations are made by comparison with other drugs or treatments, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, quotations, or other references.

21 C.F.R. § 202.1(e).

42. The FDA interprets the term "advertisement" broadly, to include not only written information promoting the product, but also oral statements made by manufacturers' sales and marketing agents. See "[FDA] Guidance for Industry: Industry-Supported Scientific and Educational Activities," 62 Fed. Reg. 64,074, 64,075-76 (1997); 21 C.F.R. §201.128.

43. This regulatory scheme protects patients and consumers by ensuring that drug companies do not make claims as to the safety or efficacy of an approved drug unless the claim is proven through scientific evidence to the satisfaction of the FDA.

V. GILEAD'S ILLEGAL MARKETING SCHEME

A. Gilead's Launch of Truvada

44. While Gilead has employed the unlawful methods described herein to promote the sales of all of its prescription drugs, the focus of its scheme since late 2004 has been the promotion of its latest HIV drug, called Truvada. Truvada is a once-daily "combination" HIV drug that includes the active ingredients found in Gilead's two other HIV drugs, Viread and Emtriva. Truvada belongs to a class of HIV drugs called "Nucleoside Reverse Transcriptase Inhibitors," or "NRTIs." The major advance that Truvada offered to HIV patients was the added simplicity and convenience of taking one NRTI pill per day, as opposed to taking two or more separate pills to achieve the same therapeutic effects.

45. The FDA approved Truvada in August 2004. Long before that, however, Gilead recognized that Truvada sales would be critical to the company's ability to compete in the lucrative HIV drug market. With that in mind, Gilead set out to plan and execute a scheme to gain market share for Truvada in as short a time as possible. As explained below, that scheme included the systematic use of illegal kickbacks, kickbacks that resulted in thousands of false and fraudulent claims for reimbursement for Truvada prescriptions.

46. Gilead knew that prescriptions for Truvada would come from one of two general types of HIV patients: (1) patients beginning HIV drug therapy for the first time (so-called "treatment-naïve patients"); and (2) patients who were currently taking other HIV drugs (so-called "switch" patients). Gilead expected that treatment-naïve patients would account for roughly one-third of its potential Truvada sales. Accordingly, most Truvada sales would have to come from "switches."

47. With respect to the switch group, Gilead's focused its efforts on patients taking Combivir, an NRTI manufactured by Glaxo. At the time of Truvada's launch, Combivir was prescribed to 28% of the 370,000 HIV patients under treatment in the U.S., and generated annual sales of $1 billion dollars worldwide. In internal presentations from that time, Gilead described Combivir patients as the "largest and most profitable market segment" for potential Truvada sales, and accordingly sought to "create a sense of urgency" among physicians to switch patients to Truvada. Exhs. 1& 2. Gilead stressed that "[i]ncreased effectiveness in switching 'stable' patients is necessary to achieve [the] year-end revenue target" and that these switches were a "major area of focus in current commercial activities." Exh. 3. In the fall of 2004, Gilead estimated the "market potential" for Combivir switches to be $815 million. In September 2005 (one year after Truvada's launch), Combivir switches accounted for 24% of all patients switched to Truvada (including patients switched from Viread and Emtriva).

48. Notably, in targeting these Combivir patients Gilead gave no consideration to whether they were doing well on their existing regime, or what risks these patients incurred in switching drugs. Indeed, Gilead explicitly acknowledged that switching "stable" Combivir patients (that is, patients who were responding well to treatment with Combivir) was critical to the success of Truvada. Exhs. 1 & 2. Gilead insisted on pushing for those switches despite substantial resistance from treating physicians, the misgivings of its own Medical Affairs Department, and the fact that its own top physician-advisors did not think Gilead's data supported such switches.

49. Gilead was also not dissuaded by the fact that third party payers would incur significant extra costs for each patient switched from Combivir to Truvada. Truvada is more

expensive than Combivir, by as much as $900 per year per patient, by Gilead's own estimation. Further, each patient switched from Combivir to Truvada requires additional physician visits that would have been unnecessary had the patient continued on the Combivir regimen (visits to begin Truvada treatment, follow-up visits to monitor patient progress and check for side effects, etc.).

50. Adding to Gilead's challenge in launching Truvada was the fact that, in 2004, Glaxo had launched its version of the once-daily combination NRTI, called Epzicom. The FDA had approved Epzicom and Truvada on the very same day; Glaxo and Gilead were therefore pursuing the very same patients (treatment-naïve patients and those already treating with older drug regimens) at the very same time with drugs that purported to offer similar benefits.

51. At the center of Gilead's scheme to promote Truvada switches was Study 934, which investigated the efficacy and side effects of Truvada as compared to Combivir. Study 934 was initially a 48-week study that began late in 2004. The results of Study 934 would not be known until late 2005, and would not be reviewed or approved by the FDA until shortly thereafter. Nevertheless, as discussed below, Gilead planned and executed a scheme to use preliminary, unreviewed and unapproved data from Study 934 to promote Truvada sales throughout 2005.

52. To help secure the switches that were critical to Truvada's success, and to overcome the strong reluctance among physicians to switch stable Combivir patients to a new treatment regime, Gilead launched the COMET "switch study," in which it paid physicians from $2,000 to $3,500 for each patient switched from Combivir to Truvada. Despite the OIG's specific warning regarding payments to physicians to switch patients' prescriptions, Gilead's intent to use COMET to do exactly that is clearly demonstrated in internal emails regarding the study. In one email David Johnson (Gilead's Senior Marketing Director), noted that "COMET is the key to the switches we need in 2005" and asked other Gilead marketing people (with apparent consternation): "We are paying them [doctors] to switch patients . . . why is this not happening?" Exh. 4.

53. Despite the cash inducements, Gilead initially had great difficulty getting physicians to enroll patients in this study. This is because, in the words of Gilead's own Medical Affairs department, doctors were "very reluctant to switch stable patients off [the competitor's

drug] even for purposes of a study," due to the inherent risks to patient health involved in switching drug regimens (especially where the current drug regimen was effective). Exh 5.

54. To overcome physicians' and patients' (very reasonable) reluctance to switch drugs, Gilead sales and marketing people searched for ways to offer further inducements to the reluctant physicians, such as (1) raising the per-patient reward from $2,000 to $2,500 and eventually to $3,500; and (2) offering physicians trips to Chicago for speaker training (as discussed above, speaker training involved all expenses paid travel and luxury accommodations as well as a cash payment of approximately $1,500).

55. Gilead's intent to use COMET as a means of paying remuneration to physicians is clearly demonstrated in a June 26, 2004 email exchange in which Bill Guyer asked Gilead sales representatives to supply recommendations for COMET study investigator sites. Beth LaVigne replied to Mr. Guyer's request: "Based on current business needs we need to go with The Care Clinic." Exh. 6 (emphasis added). Of course, manufacturers may not legally choose study sites based on "business needs."

56. In addition to offering cash to physicians to switch their patients to Truvada, Gilead offered patients a six-month supply of free drugs, in the hope that this free drug period would operate as a hook to get these patients to continue with Truvada once the study period.

57. Eventually, by raising the cap on the number of patients each physician could enroll, and by raising the cash payoff for each patient switched, Gilead was able to reach its targeted enrollment of 411 patients. Accordingly, Gilead paid its top physician-customers over one million dollars in investigator fees alone.

58. In addition to these per-patient payments, Gilead held "investigator updates" for COMET investigators. One such meeting was held live in Washington, D.C. in October 2004, and included 200 prescribers, each of whom was paid a cash honorarium to attend, in addition to travel and accommodations. Other updates were held via telewebs, for which investigators were paid $200-$300 to dial in and listen to promotional information about Truvada. These updates provided Gilead the opportunity to funnel more remuneration to these investigator-physicians.

59. These updates provided Gilead with yet another opportunity to push Truvada promotional information to its customers. In internal presentations Gilead refers to COMET investigator meetings as one of several methods it will employ to "establish a rationale" among physicians to "drive switches" from Combivir to Truvada. Exh. 7. The slides presented at these updates are geared toward selling the investigators on the superiority of Truvada over other HIV medications.

B. Gilead's Illegal Kickbacks

60. Since 2001, Gilead has systematically violated federal and state anti-kickback laws in its promotion of Truvada and other drugs by the use of sham "personal services" contracts and sponsorship of Continuing Medical Education ("CME") programs. Gilead has used these vehicles to funnel substantial cash and non-cash remuneration to hundreds of prescribers, both to induce prescriptions directly, and also to induce them to attend Truvada promotional presentations. Gilead uses these captive audience presentations to disseminate not only FDA-approved claims and information about Truvada, but also claims that Gilead was forbidden to make in its overt drug marketing, because they were outside Truvada's label and were not FDA-approved. Thus, the programs serve the dual unlawful purpose of circumventing anti-kickback statutes as well as FDA regulations on prescription drug marketing. In essence, Gilead paid physicians to listen to sales "details" that included both approved and unapproved promotional information.

61. Gilead's illegal inducements reached hundreds (if not thousands) of HIV prescribers in the United States, and caused those prescribers to write new prescriptions for Gilead drugs and to switch stable patients from Combivir to Truvada. In addition, Gilead focused special attention on a select subset of those physicians who were particularly important to its drug sales, because they had especially large patient populations, or had special influence over other prescribers, or had publicly challenged Gilead's marketing message. These physicians received very substantial remuneration from Gilead, in the form of speaking honoraria, stipends for their membership on special "advisory boards," or fees for authoring CME program materials.

62. These inducements were intended to, and did in fact cause prescribers to switch stable patients from Combivir to Truvada.

1. Personal Services Contracts

63. Since 2001 Gilead has transferred millions of dollars in cash and non-cash remuneration to hundreds of the top HIV prescribers in the U.S. These payments have the purpose and effect of inducing those prescribers to write more prescriptions for Gilead drugs. Because making such payments overtly to influence prescribing behavior is plainly illegal under the Anti-Kickback Statute, Gilead set up programs to disguise its illegal kickbacks as payments made pursuant to legitimate business relationships with prescribers. These arrangements take the form of agreements to speak on behalf of Gilead, or to provide consulting services, or to act as investigators for Gilead drug studies.

64. While these arrangements are designed to appear to fit within limited safe harbor exceptions to the Anti-Kickback Statute, in practice they do not meet the applicable standards of legitimacy, and operate as little more than a means for Gilead to funnel kickbacks to a large percentage of its prescriber-customers.

65. The scope of Gilead's scheme is very broad—by use of personal services contracts Gilead has made substantial cash and non-cash payments to at least 70% of the Decile 10 prescribers in the U.S. (the top 66 prescribers), 60% of Deciles 9-10 (the top 186 prescribers), and 50% of Deciles 8-10 (the top 350 prescribers).

a. Speaker Training and Speaker Telewebs

66. Gilead approaches and secures contracts with hundreds of physicians, ostensibly for the purpose of getting them to speak promotionally about Gilead's products to other health professionals, and/or to speak as presenters at CME events sponsored by Gilead. Gilead then purports to train these physicians, most often at large bi-annual meetings called "speaker training events," and sometimes on a one-on-one basis. In connection with these events, physicians typically receive $1,500 in cash, in addition to travel expenses, luxury hotel accommodations, meals and entertainment.[1] Gilead refers to its roster of speakers as its "Speakers Bureau."

[1] The OIG Guidance and PhRMA Code generally restrict the provision of meals, and prohibit manufacturers to provide travel or entertainment, to prescribers. Exceptions are made for those prescribers that the manufacturer legitimately employs, as speakers, consultants etc. Because Gilead's speaker, consultant and investigator arrangements are not bona fide business relationships (as described below), the prescribers who receive meals, entertainment and travel

67. In addition to these bi-annual training events, Gilead holds periodic "teleweb updates" for its Speakers Bureau. Physicians receive these updates via telephone and/or the internet, and typically receive a $250 - $300 honorarium for each session. They are not required to perform any work to receive the payment; they may simply dial in and listen to the presentation. A typical teleweb update follows a major HIV/AIDS conference, and provides the speakers with Gilead-friendly data that was covered at the conference. For its February 2005 teleweb update, Gilead invited 307 speakers; nearly 100 attended and received their honoraria. By using these updates, Gilead can funnel even more cash to its customers, and present them with even more (otherwise restricted) promotional information.

68. Under federal regulations and the PhRMA code, a manufacturer may contract with a limited number of physicians to provide bona fide services, such as speaking to other health professionals about the manufacturer's products, without violating the Anti-Kickback Statute. However, a manufacturer may use such services contracts only for bona fide business reasons; it may not use them to transfer remuneration to physicians to increase the number of prescriptions for the manufacturer's product. If even one purpose of the services contract is prohibited, the arrangement violates the Anti-Kickback Statute. In addition, federal regulations set forth requirements that a personal services contract must meet in order to qualify for safe harbor protection from the prohibitions of the Anti-Kickback Statute. Among those requirements are that the manufacturer must not "retain" more physicians than it reasonably requires to perform the particular service and that the services provided under the contract do not involve an activity that violates state or federal law.

69. Perhaps the clearest evidence that Gilead uses speaker training for the purpose of paying illegal kickbacks to prescribers is the fact that it retains and trains as many as 360 speakers at one time—many more than it legitimately requires or can even put to use. Federal regulations require that, to qualify for the exception for legitimate business service contracts, the manufacturer may contract with only as many physicians as are "reasonably necessary to accomplish the

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pursuant to these sham relationships do not qualify for this exceptional treatment, and instead are subject to the same limitation and prohibitions as the general population of prescribers.

commercially reasonable business purpose of the services." 42 C.F.R. § 1001.952(d). The PhRMA Code explicitly provides that the number of physicians retained as speakers must be consistent with the number actually required to perform speaking services. PhRMA Code, Ex. A, Example J ("if significantly more participants were trained than were to be used as speakers, this arrangement would not comply with the Code'"). Gilead's internal rules –which purport to adopt the PhRMA Guidelines—require that every physician who receives speaker training (and its appurtenant cash and non-cash benefits) speak at least two times per year.

70. While the twice-per-year requirement seems to be a modest one, the majority of Gilead's Speakers Bureau does not meet it. In 2005, nearly half of the 360 speakers did not give even one talk, and as many as two-thirds of the speakers did not meet the twice-per-year requirement. During a presentation at a recent National Sales Meeting, Elaine Hen (Gilead's Manager of Opinion Leader Programs) acknowledged Gilead's failure to comply with the speaker frequency guidelines, and admitted that many physicians attend speaker training events just to get free travel accommodations and cash honoraria.

71. The fact that Gilead "trains" far more physicians than it actually needs is further evidenced by the fact that vast majority of Gilead speaking engagements are performed by a small minority of the Speakers Bureau. Of the 467 speaking engagements in 2005, more than half were performed by just 38 physicians (10% of the Speakers Bureau), and roughly 85% were performed by just 106 speakers (29% of the Bureau). These statistics indicate that a reasonable number of speakers would approximate 100, as opposed to the 360 on Gilead's Bureau. At a minimum, Gilead could cut its Speakers Bureau in half and suffer no loss of ability to fill its speaking slots.

72. Instead of taking that action, however, Gilead continues to permit trainees to remain on the Speakers Bureau despite their failure to speak, and continues to train and re-train these non-speaking speakers (and repeatedly pay them the appurtenant cash and non-cash remuneration). [redacted] In light of the failure of most of Gilead's trained speakers to complete the mandatory two talks per year, the only reason to fill speaker training events to

capacity is to ensure that the remuneration and promotional material provided at these events reached as many prescribers as possible.

73. In addition to training 360 "promotional" speakers, Gilead has provided special training to 180 physicians for Gilead-sponsored CME speaking engagements. Gilead calls this its "Simply Speaking" program. The 180 Simply Speaking trainees were a sub-set of the promotional Speaker Bureau, and the Simply Speaking training took place in October 2005 on the day following the promotional speaker training, at the same New York luxury hotel. The Simply Speaking trainees received an additional $1500 honorarium for this second day of training. While the Simply Speaking program is relatively new for Gilead, Relator believes that, as with the promotional Speakers Bureau, the majority of the Simply Speaking trainees will not do any actual speaking. Rather, Gilead is using the Simply Speaking program as yet another vehicle to deliver inducements and promotional information to its targeted physician-customers.

74. The fact that Gilead contracts with vastly more physicians than it requires or utilizes vitiates any safe harbor protection that Gilead hoped to secure for these contracts, and exposes the remuneration (cash, travel, etc.) paid thereunder for what it is – illegal kickbacks paid to induce prescriptions for Gilead drugs.

75. Further evidence that Gilead employed its speaker training program for the illegal purpose of funneling remuneration to prescribers to induce them to write Gilead prescriptions includes the following:

- In a February 2005 email, Gilead's Director of Medical Education—Bill Guyer—described the upcoming speaker training program (with 250 attendees) as Gilead's "premier promotional event of the year." Exh. 9 (emphasis added).
- In a March 17, 2005 email, David Johnson (Gilead's Senior Marketing Director for HIV) suggested that Gilead invite physicians to the upcoming Chicago speaker training event to attempt to induce them to enroll patients in the COMET study –a study in which Gilead would pay prescribers up to $3,500 for each patient switched from Combivir to Truvada. Exh. 4.

- Gilead conducts "return-on-investment" analyses after speaker training events. Immediately following one 2005 teleweb training event dedicated to pushing positive messages regarding Truvada and Study 934, Gilead performed an "instant" return-on-investment survey, polling the attendees on whether the data presented would affect their tendency to prescribe Truvada. Exh. 10.
- Gilead received feedback from speaker trainees that an October 2005 training session on switching patients to Truvada included "too much marketing" – of course, these training sessions are not supposed to include any "marketing" at all. Exh. 11.

b. Consulting Program

76. At any one time, Gilead retains as many as 400 consultants and advisors. While the ostensible purpose for these arrangements is for Gilead to gain feedback from key physicians to help it guide its scientific and business activities, in practice the consulting program is primarily a means to deliver remuneration to physicians for prescribing Gilead drugs and attending Gilead promotional presentations. Gilead holds numerous meetings each year with its consultants and advisors—generally at least two large "Regional Consultant Meetings" ("RCMs"), each of which is attended by approximately 200 consultants, and numerous other supplemental meetings throughout the year. For each of these meetings, consultants receive $1,500 cash, along with luxury travel accommodations, meals and high-end entertainment. After it completes its promotional presentation, Gilead asks that its "consultants" answer a few basic questions, such as how the presentation would affect their prescribing practices and what additional information they would need to view Gilead's products more favorably.

77. In addition to these numerous meetings, Gilead holds frequent "teleweb" updates for its consultants, for which participants are paid $250 - $300 or more to call in to view and listen to Gilead promotional information. Like the RCMs, the telewebs end with the attendees answering questions about what impact the presentation had on their prescribing decisions. Many of these "questions" were written to reinforce the marketing message that had been delivered at the consulting meeting.

78. A manufacturer may legitimately employ a modest number of consultants gain feedback to guide its business strategies. What Gilead has done, however, is simply to designate hundreds of its top customers as "consultants" as a way to legitimize payments to induce prescriptions and to get them to attend promotional presentations.

79. As with the Speakers Bureau, the clearest evidence that Gilead uses consultants for something other than its stated purpose is the fact that it employs many times the number of consultants as it needs to accomplish that purpose. Indeed, while the PhRMA Code cites fifteen as a "reasonably small" number of physicians for a manufacturer to employ as consultants (PhRMA Code, Exh. A, Question (i) and Answer), at any one time Gilead employs as many as 400. Included in that 400 are nearly 50% of the top 350 prescribers of HIV medications in the U.S. (Deciles 8-10).

80. Gilead acknowledges that the Anti-Kickback Statute requires that it retain only a commercially reasonable number of consultants, and that each consultant retained must be able to provide unique and commercially valuable feedback. Gilead could not reasonably require (or obtain) uniquely valuable feedback from each of these hundreds of physicians. Accordingly, Gilead spends great effort to craft justifications for the retention of each of its hundreds of consultants. Indeed, when Gilead sales representatives are asked to forward names of physicians to target as potential consultants, they are given model justifications to create a record of the purported "unique" perspective each physician will provide. Despite these pre-packaged justifications, however, it is clear that Gilead could not be receiving unique and valuable feedback from so large a number of physicians.

81. The fact that Gilead's consulting program operates as an illegal kickback vehicle, and not as a means for Gilead to secure legitimate business advice, is further evidenced by the following:

- Gilead is intent on filling every slot available at consulting meetings; it keeps back-up attendee lists and over-books the meetings on the expectation that a certain number of invitees will not attend. The fact that Gilead is so focused on the number of physicians attending, rather than on the particular perspective each

attendee can offer as a consultant, is evidence that the purpose of these events is to ensure that Gilead's inducements and promotional messages reach as many prescribers as possible.

- Gilead spends large sums of money on a small number of outside consultants and focus groups, and uses feedback it receives from these efforts to direct its marketing activity. Relator believes that Gilead uses the feedback it obtains from these bona fide outside consultants to craft the promotional messages it will deliver to the hundreds of sham consultants at the much larger RCMs and other consulting meetings.
- The content of the RCMs also makes clear that they are meant to push promotional information to, rather than to gain feedback from, the audience. A typical RCM includes an extensive slide presentation of data regarding Gilead drugs (and competitors' drugs), followed by a short "feedback" session where Gilead asks the attendees what affect the presentation will have on their prescribing practices, and what additional information they would like to see regarding Gilead products.
- In some cases, the consultants and advisors themselves have noted (in post-meeting feedback) that the purported consulting sessions are more like Gilead marketing presentations. Consultants have suggested that Gilead be more "up front" about the "marketing" aspect of the meetings (instead of disguising it as "science"), and that Gilead "not ask leading questions" because "they are insulting." Exh. 12.
- To track the impact of its RCM marketing presentations, Gilead has required RCM attendees to respond to a questionnaire, at the conclusion of the event, which asks whether they will change their prescribing practices based on what promotional information was presented to them.
- Gilead spends great effort tracking their return on investment from each RCM. The "return" that Gilead seeks from its RCMs is not the consultants' legitimate feedback regarding Gilead drugs, but rather their "buy-in" of Gilead's sales message, and a change in their prescribing habits in favor of Gilead drugs. [redacted]

[redacted]

- Gilead chooses its consultants based not on legitimate reasons –their "expertise in the areas where their advice is needed" (PhRMA Code, Ex. A)—but rather on their potential worth as Gilead customers. [redacted]

- [redacted]

- [redacted]

- In an October 25th, 2004 email, Bill Guyer stated that at a particular upcoming RCM Gilead needed to elicit feedback from its "consultants," in contrast to

"previous programs where we data dump" (emphasis added). Exh. 17. This appears to be an admission that Gilead used RCMs not to get advice from consultants, but rather as a means to pay prescribers to listen to promotional information.

- [redacted] This demonstrates that Gilead used RCMs as a means of delivering a sales message to customers, rather than as a means of eliciting feedback from consultants.
- [redacted].

82. Gilead's sham consulting program has played a central role in its marketing of Truvada. In August 2004 Gilead abruptly switched its November 2004 RCM to September, in order "to support the launch" of Truvada. In making the schedule change, Gilead's Vice President of Sales noted that "we cannot wait until November (as currently planned)." Exh. 20. The reason for the change in schedule was the launch of Glaxo's competing drug (Epzicom) in the fall of 2004, and Gilead's perceived need to combat that marketing push with its own. The RCM (and the chance to get remuneration and off-label information to physicians who were being courted by Glaxo) was considered a cornerstone of that marketing assault.

83. The sheer number of Truvada-related consulting events in 2005 is telling. In the Spring of 2005 Gilead held an RCM in Chicago at which approximately 200 RCs attended. In November 2005 Gilead held another RCM in Phoenix, with another 200 attendees. In addition to those, Gilead arranged for even more RCMs to follow the Phoenix RCM, to reach any important

customers that could not make the Phoenix meeting. These RCMs were supplemented by several teleweb events with consultants.

c. Drug Studies

84. Gilead contracts with hundreds of physicians to act as investigators for its drug studies. Here again, it is permissible for a manufacturer to arrange for physicians to act as investigators, and to pay them a fair market fee for their services. However, Gilead has used drug studies as additional vehicles to funnel kickbacks to physicians to prescribe its drugs and listen to its promotional presentations.

85. The clearest example of Gilead's scheme to use drug studies to pay physicians to switch patients to switch to Truvada is the COMET study, discussed above. Additional evidence that Gilead uses drug studies as a means to pay inducements to physicians includes the following:

- In a January 2004 email, Bill Guyer told Clifford Samuel (a Gilead sales director) that Dr. Michael Weinstein "will probably ask again about contracting" with Gilead, and instructed Samuel to respond by reminding Dr. Weinstein "of all that we are already doing for him and [his foundation]," including "that we were able to add him to our current study 934 as a site and they are doing well." Exh. 21.
- In 2004 Gilead reconsidered its decision not to fund a study proposed by Dr. Fasiha Kanwal, when it realized that (1) the grant request was supported by another prominent physician who was "a good friend to Gilead," and (2) Dr. Kanwal was affiliated with the Veteran's Administration and could therefore help Gilead with V.A. drug formulary decisions. Exh. 22.
- In April 2004 Gilead launched a Phase IV study, and tapped Dr. Khanlou as the "Principal Investigator," not because of a need for clinical information or because of Dr. Khanlou's expertise, but for the purpose of getting Dr. Khanlou to increase his prescriptions of Gilead drugs. Bill Guyer later boasted about how Dr. Khanlou's Gilead prescriptions did in fact increase dramatically as a result of this outreach.

- In an internal presentation Gilead stated that a key goal for its Medical Education department is to place studies "with key (or potentially key) investigators" and to "establish stronger alliance with our key customers." Exh. 23 (emphasis added).
- In an annual employment review, Gilead praised Bill Guyer for using studies as a means of "selling" Gilead data to the study investigators to induce those investigators to sell more Gilead drugs: "Bill also uses this time [discussions with investigators about their drug studies] to talk with potential investigators to help discuss the current data, which helps better position the portfolio of drugs for a return immediately, since these potential investigators are also prescribers." Exh. 24 (emphasis added).

d. Illegal Advertising and Promotion

86. Gilead's attempt to cloak kickbacks as legitimate payments, made pursuant to these safe harbor "personal services" arrangements, fails for an additional reason. Under anti-kickback regulations, a personal services contract is not entitled to safe harbor protection if it involves "the counseling or promotion of a business arrangement or other activity that violates any State or Federal law." 42 C.F.R. §1001.952(d)(6). Gilead's speaker training, consulting and drug investigator programs violate federal drug advertising laws, because Gilead uses the programs to disseminate misleading and non-labeled promotional claims and information, claims that Gilead knew it was forbidden to make in advertising its drugs.

87. Gilead knew that it was prohibited from making certain claims and using certain information in its promotion of Truvada. For example, it could not advertise the results of Study 934 until those results were reviewed and approved for Truvada's label by the FDA, and it could not make claims that Truvada was "superior" to Combivir, because it had not completed the two head-to-head studies required to support such a claim.[2] Indeed, in internal presentations Gilead admitted that it "may not incorporate off label information into promotion," and defined

[2] In a February 2006 interview Gilead's CEO, John Martin, stated (falsely) that, with the FDA's recent approval of Study 934, Gilead was "prepared for first time to use [Study 934] data for our sales efforts" (emphasis added). In fact, at the time of Martin's interview, Gilead had been using Study 934 "for its sales efforts" for over one year.

"promotion" as "claims made with [the] intent of persuading someone to purchase" its drugs. Exh. 25. But Gilead nevertheless disseminated these "restricted" claims and information to its physician-contractors, such as speakers, consultants and study investigators, ostensibly because they needed this to effectively speak on behalf of Gilead or provide consulting services or conduct drug studies. The true purpose, however, was to push to hundreds of top prescriber-customers the very message about Truvada that it was prohibited from disseminating "promotionally":

- Internal presentations from 2005 stress the importance of using speaker training, consulting meetings and investigator updates to push the message of Truvada's superiority and to disseminate early results from Study 934. See, e.g., Exhs. 3, 7, 26.
- A May 2005 presentation regarding Gilead's Medical Education department's priorities included a reference to Gilead's plan to sell the idea of Truvada's superiority, despite Gilead's inability to use Study 934 data "promotionally," by "[t]rain[ing] speakers on superiority analysis of [Truvada] over [Combivir] in 934 through live meeting, telewebs, and video-based website." Exh. 26.
- In October 2005 Gilead's speaker training event focused on selling the 220 attendees on the "superiority of Truvada over Combivir," based on the results of Study 934. Exh. 27.
- In late 2004, a draft presentation entitled "Medical Education Overview" included a reference to using a speaker training update to help "establish a rationale" among prescribers for switching stable patients from Combivir to Truvada. Exh. 7.

88. Thus, with its speaker training, consulting and investigator programs, Gilead had both (1) a paid, captive audience for its promotional messages (an audience of hundreds of its top customers) and (2) legal "cover" for pushing otherwise restricted promotional information to those key customers. Because Gilead deliberately used its personal services arrangements to make an end run around federal drug advertising regulations, it cannot use those arrangements to justify its

payment of millions of dollars in cash and non-cash remuneration to the providers of those services. 42 C.F.R. §1001.952(d)(6).[3]

2. Illegal CME "Sponsorship"

89. In addition to using sham personal services contracts to evade anti-kickback laws, Gilead has employed CME sponsorship[4] as a means to funnel remuneration to thousands of physicians and other prescribers, to induce them to prescribe Truvada and other Gilead drugs and to attend Gilead promotional presentations. Gilead funds CME programs through "unrestricted educational grants" to various CME providers. For 2005, Gilead spent over $4 million on CME sponsorship.

90. Some of these grants are for "live" CME programs. For example, for 2006 Gilead has given a large grant to Rush University Medical Center to manage Gilead's "Simply Speaking" CME programs. These programs are presented at live dinner meetings, at AIDS clinics, or via telewebs. As of the date of this filing, there are five distinct Simply Speaking programs on five topics on which Gilead is focusing its marketing efforts. Gilead sales representatives go into the field and sell these programs to potential hosts (physicians, clinics, AIDS service organizations, etc.).

91. Other sponsored CME programs are reduced to writing or electronic form (so-called "enduring" programs), and can be viewed by individual physicians at their convenience. Gilead works with several providers to produce these programs, which (like the Simply Speaking programs) are tailored to topics that Gilead believes will boost the sales of its drugs. Sales representatives are required to market these programs to physicians. Until recently the various programs were presented together in a "menu" fashion to physicians, but to increase enrollment Gilead now distributes each program brochure individually.

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[3] It is important to note that this is a separate basis for denying a safe harbor exception for Gilead's sham personal services arrangements. Even if Gilead had disseminated only approved, labeled information to its speakers, consultants and investigators, those programs would nevertheless violate the Anti-Kickback Statute because they do not meet other safe harbor requirements and, more importantly, are set up for the purpose of funneling remuneration to prescribers to influence their prescribing decisions.

[4] In addition to CME programs for physicians, Gilead sponsors continuing education programs for other practitioners, such as nurses and pharmacologists.

92. Another major category of Gilead's CME sponsorship is post-conference "fax blasts." Gilead contracts with a purportedly neutral third party to create synopses of the presentations Gilead made each day at a particular conference. Those updates are then distributed (often by facsimile) to thousands of prescribers at the end of each conference day. A recipient of the update need only read the faxed information to receive CME credits, underwritten by Gilead.

93. By sponsoring CME programs, Gilead provides thousands of prescribers with free CME credits, credits that are essential to maintaining their professional licenses. Absent Gilead's sponsorship, these CME credits would cost prescribers as much as hundreds of dollars per unit.

94. The OIG recognized the potential that manufacturers would use CME sponsorship for improper motives—to induce physicians to prescribe their products and to listen to their promotional presentations—and warned that "[m]anufacturers should take steps to ensure that neither they, nor their representatives, are using [CME sponsorship] to channel improper remuneration to physicians or others in a position to generate business for the manufacturer or to influence or control the content of the program." OIG Guidance, at 23738.

95. The OIG further admonished manufacturers to "be mindful of the relevant rules and regulations of the Food and Drug Administration" regarding CME sponsorship. The FDA forbids manufacturers to use CME sponsorship as a marketing tool, and requires that sponsoring manufacturers refrain from exercising influence over such aspects of CME programs as content, speaker selection, advertising and promotion.

96. Despite these restrictions, Gilead has made CME sponsorship a cornerstone of its Truvada marketing scheme by using it to (1) provide valuable CME credits to key prescribers, free of charge, and (2) deliver promotional information to those prescribers regarding Gilead drugs. Specifically, despite acknowledging that the use of CME sponsorship to disseminate non-labeled claims and information was illegal, Gilead repeatedly discussed the importance of CME programs in selling prescribers on Truvada's superiority, in order to "drive switches" to Truvada from Combivir. Gilead accomplished this goal by pushing non-labeled and non-approved promotional claims to thousands of prescribers, under the guise of neutral, educational programs.

- An October 2004 letter from a CME provider (WebMD) refers to Gilead's request for "proposed tactics to fulfill [its] overall 2005 strategy for Truvada." Exh. 28. The proposal includes numerous options for Gilead-sponsored CME activities that would advance that Truvada strategy.
- A 2004 presentation by another CME provider (HLR Communications) to Gilead makes very clear that the focus of CME sponsorship is the dissemination of promotional information, rather than the education of HIV treaters. In this presentation, HLR set forth a plan to (1) create materials that would reflect Gilead's promotional priorities; (2) pay physicians to review and comment on those promotional materials, as consulting "faculty" (HLR actually placed quotation marks around the word "faculty"—an apparent admission that these physicians were faculty in name only); and then (3) "spin" the results of that feedback into CME materials that could be used to further disseminate Gilead's promotional message. HLR's proposed (illegal) tactics pleased Gilead; it was awarded a contract to manage a very large portion of Gilead's CME sponsorship for 2005 and 2006. Exh. 29.
- An internal Gilead presentation in October 2004 listed CME programs as one method Gilead would use to "differentiate and build the Truvada brand name to ensure maximum and rapid penetration," and "switch [a] significant number of Combivir patients to Truvada." Exh. 30.
- Gilead's Medical Education Director, Bill Guyer, made it one of his personal "2004 Goals and Objectives" to "[s]upport switching Combivir patients through CME case studies." Exh. 31.
- At Gilead's most recent National Sales Meeting, Mr. Guyer stated that the main purpose of Gilead's CME sponsorship was the dissemination of off-label drug information to current and prospective prescribers. Used in this manner, CME sponsorship is tantamount to an illegal kickback – the provision of something of

value to induce a physician to prescribe Gilead drugs or to listen to Gilead promotional presentations.

- In another recent presentation, Gilead sales representatives were reminded that the menu of Gilead-sponsored CME programs "is another value added product that Gilead has to offer your customers." Exh. 32.
- [redacted]
- In a recent voicemail to all Gilead sales representatives, Bill Rich (Gilead's Senior Regional Director), described the CME programs Gilead sponsors as "Silent Salesmen" for Gilead products.
- In a March 2005 email, David Johnson (Gilead's Senior Director for HIV Marketing) asked Bill Guyer (Medical Education Director) what programs Gilead planned to help disseminate data from Study 934, which was being presented at upcoming HIV conferences. Mr. Guyer assured Mr. Johnson that, among other things, Gilead had CME-accredited post-conference updates planned, and would like to plan more CME "dinner programs." Exh. 33. This email exchange clearly demonstrates that Gilead used its CME sponsorship to support its marketing function.
- [redacted]

97. The fact that Gilead's CME sponsorship is motivated by promotional (rather than educational) considerations is further demonstrated by Gilead's total disregard for federal, industry and even its own internal guidelines. Indeed, contrary to those guidelines, Gilead exercises almost complete control over all key aspects of the CME programs it sponsors.

98. Program Content: The clearest evidence of Gilead's use of CME sponsorship as a marketing tool is the nature of the content of Gilead-sponsored programs. Without exception, these "educational" programs align neatly with Gilead's marketing and promotional priorities. Indeed, a recent presentation regarding Gilead's CME sponsorship stated that Gilead needed to "ensure" it was "prioritizing those programs that are aligned with Gilead's interests." Exh. 32. Ironically, the same slide in that presentation referred to ACCME guidelines, which expressly prohibit a sponsoring manufacturer to make its funding decisions based on the "alignment" of the programs with the sponsor's marketing interests. In addition, Gilead exercises more direct control over program content by being closely involved with the preparation of the enduring CME materials and the "slide kits" that comprise the bulk of the content for live CME programs.

99. One of the priorities in Gilead's CME sponsorship scheme in 2005 was the use of CME programs to disseminate results from Study 934 to help boost sales of Truvada, and specifically to push the switching theme that was so crucial to Gilead's marketing plan. For example, in September 2005 (months before the FDA would review Study 934 results) Gilead sponsored a CME "monograph" called "Switch or Settle." The monograph was written by Dr. Joel Gallant, a physician with close financial ties with Gilead, and the chief investigator for Study 934. Included in the discussion was a large chart (and accompanying text) showing that Truvada was superior to Combivir in terms of adverse side effects, such as anemia and nausea. Similarly, Gilead's Simply Speaking programs have thus far focused on messages that are central to the promotion of Truvada. Exh. 35.

100. In addition to exercising direct control over program content, Gilead exercises indirect (but nevertheless very effective) control through its financial relationships with program faculty (i.e., the physicians who author the CME programs). Many of the authors of Gilead-sponsored CME programs receive thousands of dollars from Gilead in their capacities as Gilead advisors, consultants, speakers and/or study investigators.

101. Selection of Presenters: In addition to its very close financial ties with CME program faculty, Gilead exercises nearly complete control over the selection of live program

presenters—in direct violation of FDA regulations, PhRMA Guidelines, ACCME Standards and even its own published internal policies.

102. For its Simply Speaking CME program, Gilead provides cash and travel accommodations for the training of the 180 speakers on the Simply Speaking roster. This training takes place at the same place as, and one day after, Gilead's promotional speaker training event. By facilitating the training of the speakers, and juxtaposing it with their promotional training, Gilead ensures that its marketing messages are communicated to the Simply Speaking presenters. These presenters can then communicate that message to CME audiences.

103. Once this roster of Gilead-trained and Gilead-friendly CME speakers is established, Gilead then ensures that its sponsored programs are presented by a member of that roster. Gilead sales representatives are instructed to "suggest" or "request" a particular speaker when they arrange for a program to take place. Because these programs are sold to program hosts as packages, the hosts have little reason to refuse Gilead's suggested speaker. Indeed, to Relator's knowledge all Simply Speaking CME programs have been presented by speakers trained and selected by Gilead. This exercise of control over speaker selection allows Gilead to exercise even more control over the content of the programs, and ensures that the programs deliver the promotional message that Gilead desires.

104. Gilead has tacitly acknowledged the illegal nature of its control over speaker selection. In a recent voicemail to all Gilead sales representatives, John Hilton (Gilead's Manager of Medical Education) instructed the sales force not to make such "suggestions" in writing.

105. Promotion and Marketing: In addition to its direct and indirect control over program content, Gilead unlawfully promotes the CME programs that it sponsors, by disseminating marketing brochures to physicians' offices (by mail, fax, or personal deliveries by Gilead sales representatives). Regulations require that a sponsoring manufacturer limit its involvement in promoting CME programs to assisting the CME provider with distribution of program announcements, brochures, etc. However, to maximize its investment in CME programs, Gilead is closely involved in their marketing and promotion. One recent presentation for Gilead's

Medical Education Group includes a reference to what Gilead sales representatives can do to better "drive traffic to" Gilead-sponsored CME programs. Exh. 36.

106. Most recently, Gilead has focused on increasing pressure on its sales force to promote and market Simply Speaking programs to Gilead's customers. [redacted]

107. Additionally, Gilead has changed its policy on its sales representatives' involvement in promoting "enduring" CME programs. Prior to this year, the policy was to have sales representatives simply deliver to physicians a binder with materials describing the various programs Gilead sponsored. However, Gilead recently determined that physicians were more likely to enroll in a CME program if the marketing materials for each program were delivered to them individually. Accordingly, Gilead has changed its policy and now instructs its representatives to hand-deliver each program brochure individually to their assigned physicians, in the hopes of boosting enrollment.

108. Audience Selection: By taking the lead in the effort to promote the CME programs it sponsors, Gilead ensures that its programs are marketed to the high-prescribing physicians that it wishes to reach with its promotional message.

3. Gilead's Use of Kickbacks to Influence Particular Prescribers

109. While Gilead used the cover of its speaking, consulting, drug study and CME sponsorship programs described above to funnel substantial remuneration to hundreds (in some cases thousands) of prescribers, it used the same programs when it needed to target specific key physicians. Gilead targeted these physicians for various reasons: some had large patient populations; some had special influence over other prescribers; some exercised control over drug formulary decisions; some had publicly challenged Gilead's marketing message and needed to be "brought in line" with that message.

110. One especially telling example of this leveraging effect is recounted in a series of emails from July 2005, in which John Hilton (Gilead's Medical Education Manager) discussed an

upcoming training seminar sponsored by the American Academy of HIV Medicine. While Gilead was not supporting the event financially, Mr. Hilton wanted to exploit Gilead's financial ties with the speaker-trainers that the Academy was using, to ensure that they had, and would disseminate, Gilead's most recent promotional information: "It is good to know that we have direct in-roads to at least ½ of the speakers they [the Academy] are using," Mr. Hilton stated, "[p]erhaps I should share this with [Regional Directors] and [Medical Science Liaisons] so they can plan 'updates' or visits with the speakers listed prior to the programs initiation." (emphasis added). Mr. Hilton noted that Gilead could accomplish this outreach because its "Medical Education team will have contact with many of the [Adademy's] presenters" via upcoming speaker training, consulting and investigator update programs. Exh. 38.

111. In addition to the programs discussed above, for certain targeted physicians Gilead implemented a "special visit" program whereby it would treat invitees to all expenses paid trips to Gilead's home office in Foster City, California. The physicians would meet with Gilead's senior management, hear Gilead's promotional message, etc. Gilead used this "special visit" tactic to turn around a number of key prescribers; in an email regarding using this tactic to turn around one intransigent physician, Gilead's Vice President of Clinical Research (Carol Brosgart) boasted that "we've done this with many other physicians." Exh. 39. [redacted].

112. Some examples of Gilead's special treatment of targeted key physicians include the following.

a. Dr. Peter Ruane

113. Dr. Peter Ruane is among the very highest prescribers of HIV drugs in the nation, and runs a large and influential HIV practice in Los Angeles. Accordingly, Gilead took special care to court and maintain favor with Dr. Ruane.

114. Dr. Ruane's relationship with Gilead is epitomized in an email from January 2004, in which Bill Guyer told Dr. Ruane that he had better start "sucking up" to Gilead if he wanted to participate in a major upcoming study. Dr. Ruane responded that he was already sucking up to Gilead every time he writes a prescription for one of Gilead's drugs. Exh. 41.

115. Shortly after the "sucking up" email exchange, Mr. Guyer discovered that Gilead had offended Dr. Ruane by neglecting to invite him to a Gilead post-conference advisory meeting. Upon learning this, Mr. Guyer wrote to various Gilead colleagues in an attempt to repair the relationship, by setting Dr. Ruane up with more paid engagements.

116. In one of these emails, Mr. Guyer noted that Dr. Ruane (1) was "the number one prescriber of Viread in the nation, while his Emtriva scripts are rising"; (2) was key to Gilead's launch of Truvada; and (3) had formerly been allied with Glaxo, before Gilead expended great effort (and presumably money) to get him to "switch camps." In his closing, Mr. Guyer did not mince words in describing the quid-pro-quo that Gilead had with Dr. Ruane: "Since [Dr. Ruane] has thrown his support behind Gilead, he would like to see us do the same in return." (emphasis added). Exh. 42.

117. Mr. Guyer suggested that Gilead (1) invite Dr. Ruane to the upcoming post-conference meeting; (2) invite him to "most, if not all, pre/post meetings for this year and years to come"; and (3) add Dr. Ruane as a "permanent Gilead Scientific Advisor." Id. In a separate email, Mr. Guyer suggested that Gilead use Dr. Ruane as the clinical lead on a new study because he "is the #1 prescriber in the Nation and it is wise to keep him happy" (emphasis added). Exh. 43.

118. Gilead quickly responded to Mr. Guyer's concerns by inviting Dr. Ruane to the post-conference meeting, inviting him to be on Gilead's U.S. Advisory Board (a position that comes with a large annual stipend), and telling him to "stay tuned" for further opportunities related to Gilead's launch of Truvada. Exh. 44.

119. Throughout 2004 Gilead continued to shower Dr. Ruane with kickbacks.

120.

121. In April 2004, Gilead's Associate Director for Phase IV Studies, John Flaherty, noted that Dr. Ruane was forming a new medical practice group and was therefore "very motivated to do Phase IV studies." Mr. Flaherty suggested that Dr. Ruane be named a lead principal investigator for the COMET study. Exh. 48.

122.

123.

b. Dr. Judith Feinberg

124. In January 2005 Gilead was considering various ways to curry favor with one important physician affiliated with the University of Cincinnati —Dr. Judith Feinberg. Dr. Feinberg had been, in Gilead's words, "challenging" because "she has not been overly supportive in her messages around Viread and now Truvada" and because of her "tendency [] to discuss the negative attributes of products." Exh. 39. She had also served on an FDA panel that rejected a previous Gilead drug called Previon.

125. In a series of emails, Gilead discussed Dr. Feinberg's importance (both her direct prescribing potential and her influence over other prescribers), and suggested a kitchen-sink approach to "offer her some other opportunities" to "further align her with Gilead," including having her (1) "participat[e] in Clinical trials" (including COMET); (2) write Gilead-sponsored CME programs (for which she would be paid fees out of Gilead's "unrestricted educational grant" to the CME provider); and (3) join Gilead's "Advisory Boards." In these emails, Gilead laments that Dr. Feinberg is not easily influenced—that she "feels she is above" taking a paid position on Gilead's Advisory Board and is not particularly interested in Gilead's COMET study. Id. In a subsequent email regarding whether to offer Dr. Feinberg a position on the U.S. Advisory Board, Bill Guyer states that "[w]e've been able to improve our relationship with her and this would be another key way to do that." Exh. 51.

126. In addition to offering Dr. Feinberg paid positions as a CME author, investigator and advisor, Gilead decided it would help turn her around by inviting her to an all-expenses paid "special visitor day" at Gilead's home office in Foster City, California. Dr. Feinberg would meet with Gilead's scientific and business leaders, and "give a noon talk" on the "HIV topic of her choice." Exh. 39.

127. Dr. Feinberg did in fact accept Gilead's invitation to join its U.S. Advisory Board, as well as its Speakers Bureau.

c. Dr. Stan Louie

128. In late 2004 Gilead became concerned about a series of presentations that one pharmacologist—Dr. Stan Louie – was giving for Glaxo, in which he stressed renal toxicity as a side effect of Viread. [redacted] In response, Gilead decided to "establish a partnership" with Dr. Louie to "minimize the damage" he was doing to Viread sales. Exh. 53. Gilead invited Dr. Louie for an all expenses paid visit to Foster City, where Gilead could present him with more Viread-friendly data, and "discuss how from a commercial standpoint we can possibly collaborate and how we can utilize him as a speaker/advisor in the future." Exh. 54.

129. Gilead's efforts were fruitful. At the end of Dr. Louie's visit, Gilead was comfortable that Dr. Louie had moderated his position on Viread's renal toxicity. Dr. Louie was invited to be on Gilead's Speakers Bureau, and had "expressed interest in continually working with Gilead." Exh. 55.

d. Dr. Paul Volberding

130. The OIG Guidance specifically warns manufacturers against paying remuneration to people who have influence over decisions regarding which drugs are approved for prescription drug formularies of government programs. Dr. Volberding is affiliated with the Veterans Administration, as Chief of Medical Services for the San Francisco V.A. Medical Center. In a February 18, 2004 email Bill Guyer offered Dr. Volberding the opportunity to "do a series of lectures" for Gilead – in Mr. Guyer's words, "You name the time and I'll make it work." In the same email, Mr. Guyer asked if Dr. Volberding would assist Gilead in getting Emtriva added to the V.A. drug formulary, a move that would greatly boost Emtriva sales. Apparently noting the less-than-subtle linkage in Mr. Guyer's email, Dr. Volberding responded: "I very intentionally have nothing to do with VA procurement as I would then be unable to have any interaction with friends like you!" Exh. 56.

e. Dr. Edwin DeJesus

131. Dr. DeJesus is among the very top HIV prescribers in the nation, and presents a clear example of how Gilead forms multiple financial ties with such prescribers to affect their prescribing decisions and to leverage their prominence to influence other prescribers as well. Dr. DeJesus is a regular paid speaker for Gilead, as well as a member of Gilead's U.S. Advisory Board. In addition, Gilead has tapped him to author of a number of Gilead-sponsored CME programs. In one email, he is referred to as one of five "usual suspects" that Gilead goes to when it needs a dependable CME author. Exh. 57. A December, 2004 email recounts a meeting between Bill Rich (Gilead's Senior HIV Sales Director) and Dr. DeJesus, in which the two discussed Dr. DeJesus' need to "walk down the middle" between Gilead and Glaxo (presumably in terms of loyalty and promotional activities), and also discussed Gilead's interest in having Dr. DeJesus speak at upcoming Gilead events. Exh. 58.

132. But Dr. DeJesus' most significant financial tie to Gilead came from his "superstar" role in the COMET study. While Gilead was having difficulty getting most of its COMET investigators to enroll any patients in the study, it lifted the per-investigator cap (from 5 patients to 20 patients) and then eliminated the cap entirely to accommodate Dr. DeJesus' prolific patient enrollment. In a January 25, 2005 email, David Johnson (Gilead's Senior Director for HIV Marketing) expressed concern about Dr. DeJesus' enrollment numbers compared to the other investigators: "It is still key to get others enrolling – we don't want it only to be Edwin [DeJesus] patients." Exh. 59. Ultimately, Dr. DeJesus was so successful at enrollment that Gilead highlighted his success in COMET newsletters to influence other physicians to enroll more patients. Exh. 60.

133. In addition, Dr. DeJesus parlayed his role in COMET into further paid engagements for Gilead. An April 2005 email refers to Dr. DeJesus as a "strong supporter of switching" from Combivir to Truvada and notes that he is "looking to speak on these issues." Exh. 61. Shortly thereafter, in July 2005, Dr. DeJesus accepted an offer to speak at a September 2005 Gilead post-conference "Investigator Meeting," for which he received travel, expenses, accommodations and a $2,000 honorarium. Exh. 62. In addition, Dr. DeJesus authored a piece touting the benefits of switching from Combivir to Truvada; that article was "blasted" to all 360 Gilead speakers in July 2005. He also authored a CME article in which he stresses the benefits of switching.

f. Dr. Joel Gallant

134. Dr. Gallant is an example of a physician that Gilead maintains financial ties with largely for the purpose of leveraging his influence among other prescribers in the HIV treatment community. While Dr. Gallant is a significant prescriber himself (Decile 7), he also is affiliated with the prestigious Johns Hopkins University Medical Center. In that capacity he is a key thought leader in the HIV treatment community, and is in a position to influence the prescribing practices of many HIV treaters.

135. Gilead's financial ties with Dr. Gallant are numerous. He is a member of the Speakers Bureau, a longtime member of Gilead's U.S. Advisory Board, and frequent author of

Gilead-sponsored CME programs. He has given numerous talks on behalf of Gilead (each for an honorarium of $2,000 - $3,000), and is frequently a speaker at key programs such as Gilead's Speaker Training and Regional Consultant meetings.

136. The return Gilead receives from its investment in Dr. Gallant (in addition to the prescriptions he writes for Gilead drugs) is illustrated at Gilead's January 2006 National Sales Meeting. At that meeting David Johnson (Gilead's Senior Director of HIV Marketing) interrupted a presentation to announce that Dr. Gallant had sent him a "heads up" regarding an "independent" press release that was being issued to announce the final results of Gilead's Study 934. That press release referred to Truvada as the "New Gold Standard," and thus incorrectly suggested that the drug had been designated as a reference point for all other HIV treatments. Exh. 63.

137. Although Gilead acknowledged that it could not directly make such overt superiority claims, it proceeded to promote them anyway by (1) sending copies of the article to approximately 5,000 prescribers (including all Decile 2 – Decile 10 physicians); (2) providing reprints of the article for its sales representatives to hand-deliver to their physicians (whether or not the physicians indicated any interest in the article or the study); and (3) purchasing print advertising in medical journals that teased physicians to "ask your Gilead representative about Study 934," thus directing prescribers' attention to the Gallant article and prompting them to ask "unsolicited" questions about Study 934. Exh. 64. Those questions would open the door for the sales representatives to discuss the article in detail.

VI. OTHER GILEAD ILLEGAL MARKETING PRACTICES

138. In addition to the practices alleged above, Relator is informed and believes that Gilead engages in other, related illegal promotional and marketing, the specifics of which Relator is presently unaware. This belief is based on (i) the pattern and practice of conduct described above and (ii) the fact that Gilead management has established a corporate climate that tolerates and encourages this conduct. As further illegal practices are identified, Relator will seek leave to amend this Complaint accordingly.

VII. GILEAD'S ILLEGAL MARKETING SCHEME ALSO DEFRAUDS PRIVATE INSURERS

139. The states of California and Illinois have enacted Insurance Fraud Prevention Acts that permit Relator to bring a qui tam action to recover for fraudulent claims submitted to private insurance companies in those states. See Counts IV and IX below.

140. Although this Complaint has focused on the impact of Gilead practices on the federal and state governments, these same practices also defraud *private* insurance companies that reimburse prescription HIV and hepatitis drugs. The practices alleged herein are systematic, nationwide practices that defraud private insurance companies in every state where defendant conducts business, including California and Illinois, on the same basis that the practices defraud the federal and state governments.

Count I
False Claims Act
31 U.S.C. §§3729(a)(1) and (a)(2)

141. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 140 above as though fully set forth herein.

142. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

143. By virtue of the acts described above, Gilead knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

144. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Government to approve and pay such false and fraudulent claims.

145. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

146. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false claims were presented by numerous separate entities, across the United States. Relator has no control over or dealings with such entities and has no access to the records in their possession.

147. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Gilead, paid and continues to pay the claims that would not be paid but for Gilead's illegal marketing practices and illegal inducements.

148. By reason of Gilead's acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

Count II
False Claims Act
31 U.S.C. §§3729(a)(7)

149. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 140 above as though fully set forth herein.

150. This is a claim for penalties and treble damages under the Federal False Claims Act.

151. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States Government, within the meaning of 31 U.S.C. §3729(a)(7).

152. As a result, monies were lost to the United States through the non-payment or non-transmittal of money or property owed to the United States by Gilead, and other costs were sustained by the United States.

153. By reason of Gilead's acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

154. Additionally, the United States is entitled to the maximum penalty of up to $11,000 for each and every false record or statement knowingly made, used, or caused to be made or used to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States.

Count III
California False Claims Act
Cal Govt Code §12651(a)(1), (2), and (7)

155. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 140 above as though fully set forth herein.

156. This is a claim for treble damages and penalties under the California False Claims Act.

157. By virtue of the acts described above, Gilead knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

158. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

159. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the California State Government.

160. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

161. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

162. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Gilead, paid and continues to pay the claims that would not be paid but for Gilead's illegal conduct.

163. By reason of Gilead's acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

164. Additionally, the California State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count IV
California Insurance Frauds Prevention Act
California Insurance Code § 1871.7

165. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

166. This is a claim for treble damages and penalties under the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7, as amended (referred to in this Count as "the Act"). The Act provides for civil recoveries against persons who violate the provisions of the Act or the provisions of California Penal Code sections 549 or 550, including recovery of up to three times the amount of any fraudulent insurance claims, and fines of between $5,000 and $10,000 for each such claim. Cal. Ins. Code §1871.7(b).

167. Subsection (e) of Cal. Ins. Code §1871.7 provides for a *qui tam* civil action in order to create incentives for private individuals who are aware of fraud against insurers to help disclose and prosecute the fraud. Cal. Ins. Code §1871.1(e). The *qui tam* provision was patterned after the Federal False Claims Act, 31 U.S.C. §§3729-32, and the California False Claims Act, Cal. Gov't Code §§12650 et seq.

168. Subsection (a) of Cal. Ins. Code §1871.7 provides for civil recoveries against persons who:

> knowingly employ runners, cappers, steerers, or other persons . . . to procure clients or patients to perform or obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured individual or his or her insurer.

169. Subsection (b) of Cal. Ins. Code §1871.7 provides for civil recoveries against persons who violate the provisions of Penal Code sections 549 or 550. Section 549 of the California Penal Code provides criminal penalties for anyone who:

> solicits, accepts, or refers any business to or from any individual or entity with the knowledge that, or with reckless disregard for whether, the individual or entity . . . intends to violate Section 550.

Section 550 of the Penal Code prohibits the following activities, among others:

> (a) It is unlawful to do any of the following, or to aid, abet, solicit, or conspire with any person to do any of the following:
>
> * * * * * *
>
> (5) Knowingly prepare, make, or subscribe any writing, with the intent to present or use it, or to allow it to be presented, in support of any false or fraudulent claim.

> (6) Knowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit.
>
> * * * * * *
>
> (b) It is unlawful to do, or to knowingly assist or conspire with any person to do, any of the following:
>
> (1) Present or cause to be presented any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.
>
> (2) Prepare or make any written or oral statement that is intended to be presented to any insurer or any insurance claimant in connection with, or in support of or opposition to, any claim or payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.
>
> (3) Conceal, or knowingly fail to disclose the occurrence of, an event that affects any person's initial or continued right or entitlement to any insurance benefit or payment, or the amount of any benefit or payment to which the person is entitled.

Cal. Penal Code § 550.

170. By virtue of the acts described in this Complaint, Gilead violated Cal. Ins. Code §1871.7(a) by knowingly employing runners, cappers, steerers, or other persons to procure clients or patients to perform or obtain services or benefits under a contract of insurance or that were the basis for claims against private insurers in the State of California.

171. By virtue of the acts described in this Complaint, Gilead violated California Penal Code §549 by soliciting, accepting, or referring business to or from individuals and entities with the knowledge that, or with reckless disregard for whether, the individuals or entities intended to violate California Penal Code §550.

172. By virtue of the acts described in this Complaint, Gilead knowingly presented or caused to be presented, false or fraudulent claims for health care benefits, in violation of Penal Code §550(a).

173. By virtue of the acts described in this Complaint, Gilead also concealed and/or failed to disclose information that would have affected the rights of patients and/or pharmacies to receive reimbursement for Gilead prescriptions, in violation of Penal Code §550(b).

174. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a health insurer represents a false or fraudulent claim for payment.

175. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

176. Private insurers, unaware of the falsity of the records, statements and claims made or caused to be made by Gilead, paid and continue to pay the claims that would not be paid but for Gilead's unlawful conduct.

177. The California State Government is entitled to receive three times the amount of each claim for compensation submitted by Gilead in violation of Cal. Ins. Code §1871.7. Additionally, the California State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count V
Delaware False Claims And Reporting Act
6 Del C. §1201(a)(1), (2), and (7)

178. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 140 above as though fully set forth herein.

179. This is a claim for treble damages and penalties under the Delaware False Claims And Reporting Act.

180. By virtue of the acts described above, Gilead knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

181. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

182. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Delaware State Government.

183. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

184. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

185. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Gilead, paid and continues to pay the claims that would not be paid but for Gilead's illegal conduct.

186. By reason of Gilead's acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

187. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Gilead.

Count VI
Florida False Claims Act
Fla. Stat. Ann. §68.082(2)

188. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

189. This is a claim for treble damages and penalties under the Florida False Claims Act.

190. By virtue of the acts described above, Gilead knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

191. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

192. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Florida State Government.

193. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

194. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

195. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Gilead, paid and continues to pay the claims that would not be paid but for Gilead's unlawful conduct.

196. By reason of Gilead's acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

197. Additionally, the Florida State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count VII
Hawaii False Claims Act
Haw. Rev. Stat. §661-21(a)

198. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

199. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

200. By virtue of the acts described above, Gilead knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

201. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

202. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Hawaii State Government.

203. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

204. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

205. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Gilead, paid and continues to pay the claims that would not be paid but for Gilead's unlawful conduct.

206. By reason of Gilead's acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

207. Additionally, the Hawaii State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count VIII
Illinois Whistleblower Reward And Protection Act
740 Ill. Comp. Stat. §175/3(a)(1), (2) and (7)

208. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

209. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward And Protection Act.

210. By virtue of the acts described above, Gilead knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

211. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

212. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Illinois State Government.

213. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

214. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

215. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Gilead, paid and continues to pay the claims that would not be paid but for Gilead's unlawful conduct..

216. By reason of Gilead's acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

217. Additionally, the Illinois State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count IX
Illinois Insurance Claims Frauds Prevention Act
740 Ill. Comp. Stat. §92

218. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

219. This is a claim for treble damages and penalties under the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. §92/1 et seq. (referred to in this Count as "the Act")

220. Subsection 5(a) of the Act provides that it is unlawful to knowingly offer or pay "any remuneration directly or indirectly, in cash or in kind, to induce any person to procure clients or patients to obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured person or the person's insurer." 740 Ill. Comp. Stat. §92/5(a).

221. Subsection 5(b) of the Act provides that any person who violates any provision of the Act or any provision of Article 46 of the Illinois Criminal Code shall be subject, in addition to any other penalties that may be prescribed by law, to a civil penalty of not less than $5,000 nor more than $10,000, plus an assessment of not more than three times the amount of each claim for compensation under a contract of insurance. 740 Ill. Comp. Stat. §92/5(b). Article 46 of the Illinois Criminal Code, incorporated into subsection 5(b) of the Act, provides criminal penalties for any person who commits the offense of insurance fraud, defined in the statute as follows:

> (a) A person commits the offense of insurance fraud when he or she knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company . . . .

720 Ill. Comp. Stat. §5/46-1(a).

222. Subsection 15(a) of the Act provides for a *qui tam* civil action in order to create incentives for private individuals to disclose and prosecute violations of the statute. Subsection 15(a) provides: "An interested person, including an insurer, may bring a civil action for a violation of this Act for the person and for the State of Illinois. The action shall be brought in the name of the State." 740 Ill. Comp. Stat. §92/15(a).

223. By virtue of the conduct described in this Complaint, Gilead committed the following acts, or aided and abetted the commission of the following acts, in violation of the Act:

(a) Gilead knowingly offered or paid remuneration directly or indirectly, in cash or in kind, to induce other persons to procure clients or patients to obtain services or benefits under a contract of insurance or that would be the basis for a claim against an insurer, in violation of 740 Ill. Comp. Stat. §92/5(a); and

(b) Gilead knowingly obtained, attempted to obtain, and caused to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim and by causing a false claim to be made on a policy of insurance issued by an insurance company, in violation of 740 Ill. Comp. Stat. §92/5(b) and 720 Ill. Comp. Stat. §5/46-1(a).

224. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a health insurer represents a false claim for payment.

225. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

226. Private insurers, unaware of the falsity of the records, statements and claims made or caused to be made by Gilead, paid and continue to pay the claims that would not be paid but for Gilead's unlawful conduct, and have been damaged thereby.

227. The Illinois State Government is entitled to receive three times the amount of each claim for compensation submitted by Gilead in violation of 740 Ill. Comp. Stat. §92. Additionally, the Illinois State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count X
Indiana False Claims and Whistleblower Protection Act
I.C. 5-11-5.5

228. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

229. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

230. By virtue of the acts described above, Gilead knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

231. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

232. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Indiana State Government.

233. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

234. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

235. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Gilead, paid and continues to pay the claims that would not be paid but for Gilead's unlawful conduct.

236. By reason of Gilead's acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

237. Additionally, the Indiana State Government is entitled to the maximum penalty of $5,000 for each and every violation alleged herein.

Count XI
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. §437 et. seq

238. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

239. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

240. By virtue of the acts described above, Gilead knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

241. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

242. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Louisiana State Government.

243. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

244. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

245. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Gilead, paid and continues to pay the claims that would not be paid but for Gilead's unlawful conduct.

246. By reason of Gilead's acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

247. Additionally, the Louisiana State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XII
Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 §5B(1), (2), and (8)

248. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

249. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

250. By virtue of the acts described above, Gilead knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval.

251. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts State Government to approve and pay such false and fraudulent claims.

252. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Massachusetts State Government.

253. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

254. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

255. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Gilead, paid and continues to pay the claims that would not be paid but for Gilead's unlawful conduct.

256. By reason of Gilead's acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

257. Additionally, the Massachusetts State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XIII
Nevada False Claims Act
Nev. Rev. Stat. Ann. §357.040(1)(a), (b), and (g)

258. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

259. This is a claim for treble damages and penalties under the Nevada False Claims Act.

260. By virtue of the acts described above, Gilead knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

261. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

262. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Nevada State Government.

263. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

264. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

265. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Gilead, paid and continues to pay the claims that would not be paid but for Gilead's unlawful conduct.

266. By reason of Gilead's acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

267. Additionally, the Nevada State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XIV

New Hampshire False Claims Act
N.H. Rev. Stat. Ann. §167:61-b(I)(a), (b), and (e)

268. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

269. This is a claim for treble damages and penalties under the New Hampshire False Claims Act.

270. By virtue of the acts described above, Gilead knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

271. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

272. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the New Hampshire State Government.

273. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

274. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

275. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Gilead, paid and continues to pay the claims that would not be paid but for Gilead's unlawful conduct.

276. By reason of Gilead's acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

277. Additionally, the New Hampshire State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XV
New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-2F-4 and New Mexico Fraud Against Taxpayers Act, 2007 N.M. ALS 40 §§ 1 et seq.

278. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

279. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act and the New Mexico Fraud Against Taxpayers Act..

280. By virtue of the acts described above, Gilead knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

281. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

282. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the New Mexico State Government.

283. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

284. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

285. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Gilead, paid and continues to pay the claims that would not be paid but for Gilead's unlawful conduct.

286. By reason of Gilead's acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

287. Additionally, the New Mexico State Government is entitled to civil penalties for each and every violation alleged herein.

Count XVI
Tennessee False Claims Act and Tennessee Medicaid False Claims Act
Tenn. Code Ann. §§ 4-18-103(a) and 71-5-182(a)(1)

288. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

289. This is a claim for treble damages and penalties under the Tennessee False Claims Act and the Tennessee Medicaid False Claims Act.

290. By virtue of the acts described above, Gilead knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

291. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

292. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Tennessee State Government.

293. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

294. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

295. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Gilead, paid and continues to pay the claims that would not be paid but for Gilead's unlawful conduct.

296. By reason of Gilead's acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

297. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XVII
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. §36.002

298. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

299. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

300. By virtue of the acts described above, Gilead knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

301. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

302. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Texas State Government.

303. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

304. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false or fraudulent claims were presented by thousands of

separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

305. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Gilead, paid and continues to pay the claims that would not be paid but for Gilead's unlawful conduct.

306. By reason of Gilead's acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

307. Additionally, the Texas State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XVIII
Virginia Fraud Against Taxpayers Act
Va. Code Ann. §8.01-216.3(a)(1), (2), and (7)

308. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

309. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

310. By virtue of the acts described above, Gilead knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

311. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

312. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Virginia State Government.

313. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

314. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

315. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Gilead, paid and continues to pay the claims that would not be paid but for Gilead's unlawful conduct.

316. By reason of Gilead's acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

317. Additionally, the Virginia State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XIX
Michigan Medicaid False Claims Act
MCL 400.601-400.613]

318. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

319. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

320. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

321. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

322. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Michigan State Government.

323. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

324. By reason of the defendant's acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Additionally, the Michigan State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XX
Georgia False Medicaid Claims Act
O.C.G.A. §§ 49-4-168 et seq.

325. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

326. This is a claim for treble damages and penalties under the Georgia False Medicaid Claims Act.

327. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

328. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

329. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Georgia State Government.

330. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

331. By reason of the defendant's acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Additionally, the Georgia State Government is entitled to the maximum penalty of $11,000 for each and every violation alleged herein.

Count XXI
New York False Claims Act
N.Y. State Fin. §§ 187 et. seq.

332. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

333. This is a claim for treble damages and penalties under the New York False Claims Act.

334. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the New York Government for payment or approval.

335. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

336. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the New York State Government.

337. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

338. By reason of the defendant's acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Additionally, the New York State Government is entitled to the maximum civil penalty of $12,000 for each and every violation alleged herein.

Count XXII
Oklahoma Medicaid False Claims Act
2007 OK. ALS 137

339. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

340. This is a claim for treble damages and penalties under the Oklahoma Medicaid False Claims Act.

341. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

342. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

343. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Oklahoma State Government.

344. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

By reason of the defendant's acts, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Additionally, the Oklahoma State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XXIII
District of Columbia Procurement Reform Amendment Act
D.C. Code Ann. §2-308.14(a)(1), (2), and (7)

345. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 140 above as though fully set forth herein.

346. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act.

347. By virtue of the acts described above, Gilead knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

348. By virtue of the acts described above, Gilead knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

349. Each prescription that was written as a result of Gilead's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a District of Columbia-funded health insurance program represents a false or fraudulent claim for payment.

350. Relator cannot at this time identify all of the false claims for payment that were caused by Gilead's conduct. The false or fraudulent claims were presented by thousands of separate entities across the District of Columbia. Relator has no control over or dealings with such entities and has no access to the records in their possession.

351. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Gilead, paid and continues to pay the claims that would not be paid but for Gilead's unlawful conduct.

352. By reason of Gilead's acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

353. Additionally, the District of Columbia Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

PRAYER

WHEREFORE, Relator prays for judgment against Gilead as follows:

1. that Gilead cease and desist from violating 31 U.S.C. §3729 et seq., and the counterpart provisions of the state statutes set forth above;

2. that this Court enter judgment against Gilead in an amount equal to three times the amount of damages the United States has sustained because of Gilead's actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of 31 U.S.C. §3729;

3. that this Court enter judgment against Gilead in an amount equal to three times the amount of damages the State of California has sustained because of Gilead's actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code §12651(a);

4. that this Court enter judgment against Gilead in an amount equal to three times the amount of each claim for compensation submitted by Gilead in violation of Cal. Ins. Code §1871.7(b), plus a civil penalty of $10,000 for each violation of Cal. Ins. Code §1871.7(b);

5. that this Court enter judgment against Gilead in an amount equal to three times the amount of damages the State of Delaware has sustained because of Gilead's actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. §1201(a);

6. that this Court enter judgment against Gilead in an amount equal to three times the amount of damages the State of Florida has sustained because of Gilead's actions, plus a civil penalty of $10,000 for each violation of Fla. Stat. Ann. §68.082(2);

7. that this Court enter judgment against Gilead in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Gilead's actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. §661-21(a);

8. that this Court enter judgment against Gilead in an amount equal to three times the amount of damages the State of Illinois has sustained because of Gilead's actions, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. §175/3(a);

9. that this Court enter judgment against Gilead in an amount equal to three times the amount of each claim for compensation submitted by Gilead in violation of 740 Ill. Comp. Stat. §92, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. §92;

10. that this Court enter judgment against Gilead in an amount equal to three times the amount of damages the State of Indiana has sustained because of Gilead's actions, plus a civil penalty of $10,000 for each violation of I.C. . §5-11-5.5]

11. that this Court enter judgment against Gilead in an amount equal to three times the amount of damages the State of Louisiana has sustained because of Gilead's actions, plus a civil penalty of $10,000 for each violation of La. Rev. Stat. §437 et. seq;

12. that this Court enter judgment against Gilead in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of Gilead's actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

13. that this Court enter judgment against Gilead in an amount equal to three times the amount of damages the State of Nevada has sustained because of Gilead's actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1);

14. that this Court enter judgment against Gilead in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of Gilead's actions, plus civil penalties for each violation of N.H. Rev. Stat. Ann. §167:61-b(I).

15. that this Court enter judgment against Gilead in an amount equal to three times the amount of damages the State of New Mexico has sustained because of Gilead's actions, plus civil penalties for each violation of N.M. Stat. Ann. §27-2F-4 and 2007 N.M. ALS 40 §§ 1 et seq;

16. that this Court enter judgment against Gilead in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Gilead's actions, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. §§4-18-103(a) and 71-5-182(a)(1);

17. that this Court enter judgment against Gilead in an amount equal to three times the amount of damages the State of Texas has sustained because of Gilead's actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

18. that this Court enter judgment against Gilead in an amount equal to three times the amount of damages the State of Virginia has sustained because of Gilead's actions, plus a civil penalty of $10,000 for each violation of Va. Code Ann. §8.01-216.3(a);

19. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Michigan has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of MI Public Act 337;

20. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Georgia has sustained because of defendant's actions, plus a civil penalty of $11,000 for each violation of O.C.G.A. §§ 49-4-168 et seq.;

21. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of New York has sustained because of defendant's actions, plus a civil penalty of $12,000 for each violation of N.Y. State Fin. § 189;

22. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of defendant's actions, plus a civil penalty of $10,000 for each violation of 2007 OK. ALS 137;

23. that this Court enter judgment against Gilead in an amount equal to three times the amount of damages the District of Columbia has sustained because of Gilead's actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. §2-308.14(a);

24. that Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act, and the equivalent provisions of the state statutes set forth above;

25. that Relator be awarded all costs of this action, including attorneys' fees and expenses; and

26. that Relator recover such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: August 16, 2007

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